K013142

Attachment 2

510(k) Summary
Dynamic Imaging Diasus

OCT - 5 2001

Submitter Dynamic Imaging Ltd

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EH54 9DR
UK

Mr Allan Findlay

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Date prepared 7 August 2001

Propriety Name of Device Diasus

Common or Usual Name Diagnostic Ultrasound System with Accessories

Classification Name	FR Number	Product Code
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO

Predicate Devices

Trade name	Manufacturer	510(k)
AU4	Biosound Asaote Inc	K#944485
AU5	Biosound Asaote Inc	K#980468
AU6	Biosound Asaote Inc	K#990360

The Diasus is of comparable type and substantially equivalent to the legally marketed Biosound Asaote Inc AU4, AU5 and AU6. It has the same technology characteristics, is comparable in key safety and effectiveness features, and all its intended uses and operating modes are available in the predicative devices.

Additional Substantial Equivalence Information is provided in the following Comparison to Predicate Devices table.

Intended Uses

The Diasus Ultrasound Imaging system is intended for performing no-invasive diagnostic general ultrasound studies. Such uses include the following; Abdominal, Cardiac, Paediatric, Small organs including, Thyroid, Parathyroid, Breast and Testes, Neonatal / adult cephalic, Peripheral vascular, and Conventional / Superficial Musculoskeletal.

Comparison to Predicate Devices

General Characteristics	Dynamic Imaging Diasus	Esaote AU6	Esaote AU5	Esaote AU4
		K#990360	K#980468	K#944485
Transducer types		Annular Array	Annular Array	Annular Array
		Mechanical Sector	Mechanical Sector	Mechanical Sector
	Linear	Linear	Linear	Linear
		Convex	Convex	Convex
		Phased Array	Phased Array	Phased Array
Frequency	5 to 22 MHz	2.5 to 20 MHz	2.5 to 20 MHz	2.5 to 20 MHz
Imaging Modes				
A				
B	YES	Yes	Yes	Yes
M		Yes	Yes	Yes
PWD		Yes	Yes	Yes
CWD		Yes	Yes	Yes
Colour Doppler CFM		Yes	Yes	
Amplitude Doppler PD		Yes	Yes	
Colour Velocity Imaging				
Combined		Yes	Yes	
Cine Loop Facility	Yes	Yes	Yes	Yes
Biopsy attachments	Linear Array	Linear Array	Linear Array	Linear Array
		Convex	Convex	
Measurements				
Distance	Yes	Yes	Yes	Yes
Area	Yes	Yes	Yes	Yes
Circumference	Yes	Yes	Yes	Yes
Monitor Size (nominal)	15 inches	15 inches	15 or 14 inches	14 or 12 inches
Programmability	Only limited by hard disk size	10 presets	6 presets	
Computer interface	Centronics output	Centronics output	Centronics output	Centronics output
	SCSI in/out port			
Printer	Yes	Yes	Yes	Yes
DICOM communications	Yes optional			
External Dimensions				
Width	500mm	580mm	540mm	500mm
Height	1268mm	11440mm	540mm	1245mm
Depth	804mm	1100mm	690mm	700mm
Standards	IEC601-1	IEC601-1	IEC601-1	IEC601-1
	IEC601-1-2			
	EN61157			
Medical Device Directive CE marked	Yes	Yes	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 5 2001

Dynamic Imaging
% R. Kent Donohue
Underwriters Laboratories, Inc.
12 Laboratory Drive
P.O. Box 13995
RESEARCH TRIANGLE PARK NC 27709

Re: K013142
Trade Name: Diasus
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: 90 IYO
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Regulatory Class: II
Product Code: 90 ITX
Dated: September 17, 2001
Received: September 20, 2001

Dear Mr. Donohue:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Diasus, as described in your premarket notification:

Transducer Model Number
P75LHF
P12LHF
P16LHF

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

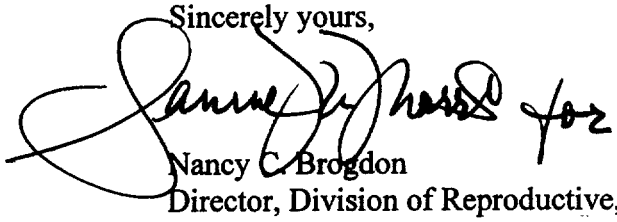
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

4.3.1 510(k) Indications for Use Form

510K number (if Known) : K013142

Device: **Diasus, Diagnostic Ultrasound System**

Intended Use : Diagnostic Ultrasound imaging of the human body as follows

	Mode of Operations									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined	Other
Opthalmic										
Fetal										
Abdominal		N								Note 2
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N								Note 2
Small Organ (Specify)		N								Note 1,2
Neonatal Cephalic		N								
Adult Cephalic		N								
Cardiac		N								
Transesophagael										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N								Note 2
Laparoscopic										
Musculo-skeletal Conventional		N								Note 2
Musculo-skeletal Superficial		N								Note 2
Other										

N = New Indication, P = Previously Cleared by FDA, E = Added under Appendix E
Additional Comments :

Note 1 For Example :
Thyroid, Parathyroid, Breast and Testes in adult, paediatric and neonatal patients

Note 2 Includes imaging for needle guidance

Prescription Use (as per 21CFR 801.109)

(Division Sign-Off)
Division of [illegible], Abdominal, and Radiological Devices
510(k) Number K013142

Indications for Use Form

510K number (If Known) : K013142

Device: **P75LHF, 5-12MHz Ultra wideband Linear Array Probe**

Intended Use : Diagnostic Ultrasound imaging of the human body as follows

	Mode of Operations									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined	Other
Opthalmic										
Fetal										
Abdominal		N								Note 2
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N								Note 2
Small Organ (Specify)		N								Note 1,2
Neonatal Cephalic		N								
Adult Cephalic		N								
Cardiac										
Transesophagael										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N								Note 2
Laparoscopic										
Musculo-skeletal Conventional		N								Note 2
Musculo-skeletal Superficial		N								Note 2
Other										

N = New Indication, P=Previously Cleared by FDA, E = Added under Appendix E
Additional Comments :

Note 1 For Example :
Thyroid, Parathyroid, Breast and Testes in adult, paediatric and neonatal patients

Note 2 Includes imaging for needle guidance

Prescription Use (as per 21CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013142

Indications for Use Form

510K number (if Known) : K 013142

Device: **P12LHF, 8-16MHz Ultra wideband Linear Array Probe**

Intended Use : Diagnostic Ultrasound imaging of the human body as follows

	Mode of Operations									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined	Other
Opthalmic										
Fetal										
Abdominal		N								Note 2
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N								Note 2
Small Organ (Specify)		N								Note 1,2
Neonatal Cephalic		N								
Adult Cephalic		N								
Cardiac										
Transesophagael										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N								Note 2
Laparoscopic										
Musculo-skeletal Conventional		N								Note 2
Musculo-skeletal Superficial		N								Note 2
Other										

N = New Indication, P=Previously Cleared by FDA, E = Added under Appendix E
Additional Comments :

Note 1 For Example :
Thyroid, Parathyroid, Breast and Testes in adult, paediatric and neonatal patients

Note 2 Includes imaging for needle guidance

Prescription Use (as per 21CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013142

Indications for Use Form

510K number (if Known) : K 013142

Device: **P16LHF, 10-22MHz Ultra wideband Linear Array Probe**

Intended Use : Diagnostic Ultrasound imaging of the human body as follows

	Mode of Operations									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined	Other
Opthalmic										
Fetal										
Abdominal		N								Note 2
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N								Note 2
Small Organ (Specify)		N								Note 1,2
Neonatal Cephalic		N								
Adult Cephalic		N								
Cardiac										
Transesophagael										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N								Note 2
Laparoscopic										
Musculo-skeletal Conventional		N								Note 2
Musculo-skeletal Superficial		N								Note 2
Other										

N = New Indication, P=Previously Cleared by FDA, E = Added under Appendix E
Additional Comments :

Note 1 For Example :
Thyroid, Parathyroid, Breast and Testes in adult, paediatric and neonatal patients

Note 2 Includes imaging for needle guidance

Prescription Use (as per 21CFR 801.109)

(Division Sign-Off)
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